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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,676	04/15/2005	Victor Sloan	PA/4-32725A	8433
1095	7590	11/17/2005	EXAMINER	
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			GRAFFEO, MICHEL	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/531,676	SLOAN, VICTOR	
	<b>Examiner</b>	<b>Art Unit</b>	
	Michel Graffeo	1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/15/05</u> . | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Status of Action***

The preliminary Amendment (Filed April 15, 2005) canceled claim 2 and amended claims 3-9. Claims 1 and 3-9 are pending and examined.

### ***Claim Objections***

Claims 3 and 7 are objected to because of the following informalities: in line 2 of claim 3 the term "oneor" needs correction. In claim 7, the terms "bx" and "mnon-" need clarification. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "at least about 2 months" is not defined in the Specification. Since the phrase is not defined, it can be interpreted such that the phrase "at least" modifies "about" as well as interpreted such that the phrase "at least" modifies "2 months". To that end, the claim is unclear since the scope of the claim can

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be interpreted to include only the time equal to or greater than 2 months as well as the time less than, equal to and greater than 2 months.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "and/or" seen in the 8<sup>th</sup> line of the claim is confusing in that it can be interpreted such that the phenyl is substituted with a lower alkyl and a halogen or the phenyl is substituted with a lower alkyl or a halogen. Whether Applicant intends both interpretations or not, the claim requires appropriate clarity.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, and 3-9 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,869,471 to Hovancik et al.

Hovancik et al. teach a method for the treatment of rheumatoid arthritis (in current claims 1,3-9; see Abstract and col 3 lines 30-32) with 1-hydroxy-2-(imidaol-1-yl)ethane-1,1-diphosphonic acid (in current claims 6-9; see col 9 lines 52-60 wherein R<sup>8</sup> is nil, Z is a 5 membered heteroatom containing one N, m is zero, R<sup>1</sup> is H, R is PO<sub>3</sub>H<sub>2</sub>

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and R<sup>5</sup> is OH) wherein treatment is administered at least 1 day of every 60 day treatment period such that the treatment periods follow one after the other (in current claims 4,5; see col 7 lines 54-60 which is interpreted to mean that two treatment periods back to back comprise 120 days and that a dose is administered at least once in each period, such that a dose can be administered on day 1 and then on day 90) and further wherein the dose administered is from 0.0005 mgP/kd (P is interpreted to mean phosphate) to 1.0mgP/Kg such that a person weighing 100kg dosed with .05mg of the bisphosphonate will be practicing the method as claimed (in current claim 9; see col 7 lines 46-53).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3 November 2005

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